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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,704	05/16/2002	Camilo Anthony Leo Selwyn Colaco	8830-21	7595

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,704	COLACO, CAMILO ANTHONY LEO SELWYN	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14,16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment and entry of the Amendment submitted on 8/18/05 is made.
Amended claims 10-14 and new claims 16-18 are currently under examination.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 18, 2005 has been entered.

Rejections Withdrawn

3. ***Claim Rejections - 35 USC § 112, second paragraph:*** The rejection of Claims 1-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been obviated in light of the amendment of the claims to delete the phrase "extacellular pathogenic organism", "immunogenic determinant", "stress inducing stimuli", "composition is an aqueous composition" and the amendment of claim 14 to recite "vaccinating" rather than "treating".

8. ***Claim Rejections - 35 USC § 102:*** Claims 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamel et al (WO 96/40928) is herein withdrawn in light of Applicant's traversal directed to the combination of reagents used in the purification process that would result in the dissociation of heat shock protein-peptide fragments and not complexes of a heat shock protein and a peptide.

Response to Arguments for Rejections Maintained

4. Applicant's arguments filed August 18, 2005 have been fully considered but they are not persuasive.

5. The rejection of claims 10-14 and 16-18 under 35 U.S.C. 112, first paragraph (Scope of enablement) is traversed on the grounds that: Applicants argue that it is not that experiment

would be necessary for the broader scope, e.g., parasites, protozoa and fungi, but that it would not be undue experimentation. Applicants argue that HSPs form a family of highly conserved proteins widely distributed throughout the plant and animal kingdom and would preserve the function. They argue that the same methods used in bacteria would work for fungi, protozoa and parasites.

5. This has been fully and carefully considered but is not deemed persuasive. It is agreed that HSP were well known in the prior art but not all antibodies directed to heat shock proteins are protective.

6. However, Applicant is arguing that they unexpectedly found that the HSPs obtained from heat stimuli and extraction formed a complex with other antigenic peptides. The claims are drawn to 'vaccines'. The prior art teaches that "it is well understood that the ability of an antigen to stimulate antibody production does not necessarily correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from infection, particularly in the case of parasitic helminthes. See US Patent 6,248,329, column 1, lines 35-45. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification,

reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." The showing of the bacterial HSP complexes is not sufficient to broadly enable any HSP complex from any protozoa, fungi or parasite, to serve as a vaccine composition, particularly when it has not been demonstrated that these complexes are formed in these organisms.

The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity. The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of vaccinating an animal against infection and disease. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

7. The ability to reasonably predict the capacity of a composition to induce protective immunity is problematic.

- Bae et al (2002) administered a trivalent protein based compositions that comprised GroEL, GroES and HtrA from Brucella abortus into mice and found an immune response induced, but it was not a protective immune response (see abstract, especially last sentence).
- Deepe et al (2002) found a heat shock protein composition from Histoplasma capsulatum to induce a protective immune response, but when administered to immunocompromised animals, protection was lost. Deepe et al concludes that induction of a protective effect against fungal burden is complex in light of the complexity of the regulatory elements necessary for vaccination against this fungus. The compositions would not serve as a

vaccine in an immunocompromised host which lacked the essential regulatory elements for induction of a protective immune response (ie CD4+ and CD8+ cells).

- Noll et al (1996) found the route of administration critical in the induction of a protective immune response when compositions comprising Yersinia HSP60 immunostimulating complexes were administered to mice. Administration of the vaccine composition induced a protective immune response by a parenteral route, but the same composition was not protective when administered mucosally.
- Turner et al (2000) found antibodies directed to Hsp60 to be induced to the Mycobacterial heat shock protein but the antibodies were not protective against "severe lung damage" resulted upon challenge.
- Leclerg et al (2002) successfully induced the production of a th1-type immune response immunoreactive against GroEL directed to Brucella abortus heat shock protein GroEL, but this immune response was not significantly protective and states "a distinct pattern of immune response was generated depending upon the immunization route used, neither method engendered a significant level of protection".
- Celine et al (2004) produced anti-GroEL antibodies that showed no neutralized effect in vitro on Chlamydophila abortus infectivity and found "mice were not protected against bacterial challenge".
- Zeilstra-Ryalls et al teaches GroEL can bind to many unfolded polypeptides (see Figure 5, page 319, ledger narrative). What antigenic peptide fragments within the scope of Applicant's claimed compositions would induce a protective immune response have not been described in the instant Specification in light of the fact that GroEL can bind and serve as a

heat shock protein chaperonin for a plurality of peptides, the nature of which many not be the induction of a protective immune response in vivo upon administration.

The reference cited above all showed antibodies to heat shock proteins, some of which were protective while other were not protective. The prior art shows that heat shock proteins are immunogenic but immune responses to heat shock proteins are not predicatively protective against the pathogen to which they were induced. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2).

Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy. Further, the specification fails to provide an adequate written description of what antigenic fragment peptides when associated with a heat shock protein would induce a protective immune response when administered to an animal, by any route, in any amount. While an immune response would be induced because heat shock proteins are known to be highly immunogenic, the skilled artisan would be required to de novo locate, identify and characterize the claimed complexes that would serve as a vaccine composition for any protozoan, fungi or bacteria. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to

other surface proteins with the claimed characteristics. The rejection is maintained for reasons of record and responses set forth herein.

4. ***(Rejection Maintained) Claim Rejections - 35 USC § 102:*** The rejection of claims 10, 11 and 13 under 35 U.S.C. 102(b) as being anticipated by Laminet et al (EMBO Journal. 1990. 9(7): 2315-2319) is traversed on the grounds that "Laminet does not teach heat-induced production of GroES or GroEL, but only constitutive expression."

8. It is the position of the examiner that at page 7, lines 29-30 of the instant Specification Applicant teaches the attainment of the invention based upon "the synthesis of stress protein occurs constitutively without the need to apply external stress". What is now claimed is a product by process composition which may be obtained by any process that produces the same or equivalent product and attainment of Applicant's claimed compositions is described to encompass constitutive express of stress proteins. Applicant's traversal is not convincing in light of the guidance, teaching and definitions for the claimed compositions in the Instant Specification.

9. Laminet et al is further traversed by Applicant by stating :

a. Laminet et al used constitutively expressed "heat shock proteins which are less immunogenic" and

b. "teaches neither the formation of a heat shock protein-antigenic peptide fragment complex, or

c. the use of such a complex to induce an immune response."

10. It is the position of the examiner that:

- the claims do not require the claimed compositions to be more immunogenic than constitutively expressed heat shock proteins. Additionally, at page 7, lines 3-5, the claimed vaccines are defined to include "any composition which stimulates the immune system such that it can better respond to subsequent infections". Therefore any level of immunogenicity, and immune response is encompassed by what is now claimed, and is not limited to the preferred embodiments exemplified in Example 3 of the instant Specification. The claimed compositions have not been distinguished from the compositions of Laminet et al which comprise the same or equivalent components, produced by a different process.

The claims are not directed to a method for the formation of a heat shock protein-antigenic peptide fragment complex, but to compositions that comprise a heat shock protein complexed with antigenic peptide fragment. The definition of "antigenic peptide fragment" in the instant Specification are defined to be "foreign antigens" to macrophages (see page 1, lines 13-14, Instant Specification). The GroEL/ES complex of Laminet et al reads on Applicant's claimed invention because the composition comprises a heat shock protein (GroEL) and an antigenic peptide fragment (GroES, produced by E.coli, a foreign antigen to mammalian macrophages) and these two components are in association with each other, specifically a complex (see abstract, page 2315, col. 1, lines 1-4).

1. It is the position of the examiner that Laminet et al was only applied to composition claims, the recited intended "use" of the complex to "induce an immune response" does not define over the applied prior art. The Laminet et al reference not only disclosed a GroEL/GroES complex, but also a GroEL/GroES/B-lactamase complex (see Figure 4, Frames A and B). The reference discloses the B-lactamase peptide to be immunoreactive with an antibody induced

thereto (see page 2319, col. 1, paragraph 4, last 4 lines). The heat shock proteins of Laminet form a "complex", see page 2315, col. 1, abstract, line 3. Additionally, Applicant's own Specification teaches heat shock proteins to be immunogenic and would therefore induce an immune response thereto, if the compositions were used for that purpose. In support for this position the examiner is also citing extrinsic evidence to Del Giudice et al (1993) who teaches microbial heat shock proteins to be immunogenic, even in infants, and the antibodies produced are directed to cross-reactive epitopes conserved across bacterial heat shock proteins (see abstract). The rejection is maintained for reasons of record and responses set forth herein. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

11. ***(Rejection Maintained) Claim Rejections - 35 USC § 102***: The rejection of claims 10-14, new claims 16-17 and 18 under 35 U.S.C. 102(e) as being anticipated by Srivastava (US 5,961,979) is traversed on the grounds that:

- "the source and structure of the Srivastava complexes are totally distinct to those obtained according to the present invention" and they are derived from
- host eukaryotic cell complexed to peptide which is derived from the preselected intracellular pathogen.

12. It is the position of the examiner that while Srivastava claims heat shock protein-antigenic peptide fragment complexes that comprise a mammalian heat shock protein non-covalently bound to an antigenic peptide from a bacteria, protozoa or fungi, but the reference discloses more than just these embodiments. The examiner agrees that the antigenic peptide

fragment in the complexes of Srivastava are those claimed by Applicant (see Srivastava col. 6, lines 41-45; col. 5, lines 20-22; col. 7, lines 3-5; col. 6, line 67).

1. Srivastava's heat shock proteins are not limited to mammalian heat shock proteins. Srivastava discloses DnaK and Hsp70 from E.coli (see col. 5, line 57), and heat shock proteins from yeast (see Table 1, col. 16, Hsp60, Hsp70 and Hsp90 from E.coli and Yeast). The heat shock proteins of Srivastava are defined as "a protein whose intracellular concentration increases when a cell is exposed to a stressful stimuli, it is capable of binding other proteins or peptides and it is capable of releasing the bound proteins or peptides in the presence of adenosine triphosphate (ATP) or low pH." (see col. 11, lines 4-10).

2. The stresses described by Srivastava include heat shock stress (see col. 11, line 13), as well as "nutrient deprivation, metabolic disruption, oxygen radicals and intracellular pathogens (col. 11, lines 20-21)."

3. The instantly claimed compositions are defined by the recited product by process limitations, but may be produced by a different process that produces the same or equivalent product. Srivastava discloses the claimed compositions produced by a different process, specifically reconstitution. The bacterial or fungal heat shock protein (see Table 1 and definitions) is reconstituted to form a complex together with a antigenic peptide fragment from a bacteria, fungus, or protozoa , wherein the heat shock protein is isolated from natural sources or recombinantly produced (see col. 21, line 28) and then complexed with the antigenic peptide fragment that has been "chemically synthesized" (see col. 21, lines 24-27)" in vitro to generate immunogenic stress protein-antigenic peptide fragment complexes.

4. The method of vaccinating a mammal (see col. 1, line 28) comprises the step of:

Administering the composition to a mammal (see col. 12, lines 21-29), wherein the complex comprises a bacterial or fungal heat shock protein (Table 1) complexed with a peptide antigenic fragment from a bacteria, protozoa, or fungus (see col. 1, line18 and col. 6, lines 41-67 and col. 7, lines 1-7) . The compositions are disclosed to comprise a pharmaceutically acceptable carrier and an adjuvant (see col. 23, lines 18-27).

5. It was noted by the examiner that Applicant's claims do not recite the term "extracellular" or "intracellular" pathogen, which are embodiments encompassed and disclosed in the instant Specification (definitions found at page 7, lines 11-20 "*extra-cellular pathogen*" and at page 8, lines 1-3 "intra-cellular pathogen) . Thus the present invention provides a method for eliciting an immune response from an animal to infection by an *intra-cellular pathogenic organism*" or an extracellular pathogen.

6. The rejection is maintained for reasons of record and responses set forth above.

7. ***(Rejection Maintained) Claim Rejections - 35 USC § 102:*** Claims 10, 11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Wallen et al (US 5,747,332) is traversed on the grounds that the complexes of Wallen et al are produced by a different process and the instantly claimed complexes are produced *in situ* within the infectious agent cell.

7. It is the position of the examiner that Wallen et al disclose at column 3, lines 49-67, the heat shock proteins may be from prokaryotes, and include the GroEl/GroEs complexes. This embodiment anticipates the instantly claimed compositions. Arguments directed to differing process steps are not convincing because the claimed products are the same or equivalent products produced by a different process. Inherently the reference anticipates the now claimed

invention.

8. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states □Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that □this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art□.

New Grounds of Rejection

9. Claims 10-11, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokota et al (1994).

Yokota et al disclose the instantly claimed invention directed to compositions that comprise:

(Instant claims 10, 16) a complex of an antigenic peptide fragment (urease, see narrative on page 403, col. 1, first whole column) associated/complexed with a bacterial heat shock protein (Helicobacter pylori heat shock protein, see title), wherein the heat shock protein is an HSP60 protein homolog.

(Instant claims 11 and 17) The composition of Yokota et al was obtained by the process of:

exposing cultured Helicobacter pylori to heat shock growth at 42 degrees C for 5, 10 or 30 minutes (see page 403, col. 2, top half of paragraph 2); and

extracting complexes from the organism (lysis at 100 degrees C, see page 403, col. 2, second paragraph).

The extract/lysed cells were produced through resuspension of Helicobacter pylori in sample buffer heated to 100 degrees C. The cell extract was found to comprise a 66 kDa protein heat shock protein at a concentration of "*about 9 times higher than those of the pretreatment*

and control preparations (see Figure 2, Table 1, page 404 and narrative on page 405, col. 1, top half of paragraph; narrative page 404, col. 1, paragraph 1; page 404, col. 2, second half of first paragraph) together with the 60 and 30 kDa proteins/peptides of the β and α chains of urease (page 404, col. 2, first paragraph).

In light of evidence provided by Evans et al (1992), (a reference incorporated by reference in Yokota et al) that teaches urease is associated in a complex with Helicobacter pylori heat shock protein (see Evans et al, page 2127, col. 1, paragraph 1; and Yokota et al, narrative in col 1 on page 403, top half of paragraph) the heat shocked Helicobacter pylori lysate of Yokota et al inherently comprises H.pylori heat shock protein-antigenic peptide fragments of H.pylori urease complexes.

Yokota et al inherently anticipates the instantly claimed invention. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states □Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that □this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

10. Claims 10-11, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Eschweiler et al (1993)

Eschweiler et al disclose the instantly claimed invention directed to a composition that

comprise a complex (see page 82, Discussion section, paragraphs 1-2) 60 k bacterial heat shock protein (Helicobacter pylori heat shock protein, see title) complexed with an antigenic peptide fragment (urease 70 k and 30k subunits). The composition of Eschweiler et al inherently anticipates the instantly claimed invention. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states □Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that □this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

11. Claims 10-11, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Austin et al (1992)

Austin et al disclose the instantly claimed invention directed to a composition that comprise a complex of a GroEL 60 k bacterial heat shock protein (Helicobacter pylori heat shock protein, see title) complexed with an antigenic peptide fragment (urease). The composition of Austin et al inherently anticipates the instantly claimed invention.

The process of making the composition was through environmental stress due to nutrient depletion (older cultures of H.pylori were characterized by increased production of the GroEL analog of H. pylori (Hp60k)) . The cells were harvested from culture and extracted with N-octylglucoside containing buffer, insoluble material was removed by regular centrifugation, and the supernatant kept (see page 7470, col. 1, paragraph 3) which comprised the heat shock protein-antigenic peptide antigen complexes ("urease remained intact as an assembly which could be separated from soluble HP60k by ultracentrifugation" ; also see page 7472, Frame C).

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states □Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that □this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Conclusion

13. This is a non-final Office Action.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. US006248330B1 ,US006576244B1 US 20040052812A1 ,US 20040047879A1 ,US 20040022796A1 US 20030211102A1 US 20030176665A1 US 20030165516A1 US006048530A US006455503B1 US005961979A US005948646A US 20030099665A1 US 20030099665A1 US 20040052812A1 US 20040022796A1 US006130059A US005948646A are cited to show various heat shock protein compositions.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
November 10, 2005

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